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ENVIRONM

[EPA-HQ-OPP-2021-0315; FRL-9790-01-OMS]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Submission of Protocols and Study Reports for Environmental Research Involving Human Subjects (EPA ICR Number 2195.06, OMB Control Number 2070-0169) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through April 30, 2022. Public comments were previously requested via the ***Federal Register*** on September 1, 2021, during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Additional comments may be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE ***Federal Register***].

ADDRESSES: Submit your comments to EPA, referencing Docket ID Number EPA-HQ-OPP-2021-0315, online using www.regulations.gov (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave., NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI),

or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Carolyn Siu, Mission Support Division (7101M), Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: (202) 566-1205; email address: *siu.carolyn@epa.gov*.

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave., NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit https://www.epa.gov/dockets.

Abstract: EPA is responsible for the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). The EPA regulations at 40 CFR part 26 protect subjects of "third-party" research (i.e., research that is not conducted or sponsored by EPA). In addition to other protections, the regulations require affected entities to submit information to EPA and an institutional review board (IRB) prior to initiating, and to the EPA upon the completion of, certain studies that involve human research participants. The information collection activity consists of activity-driven reporting and recordkeeping requirements for those who intend to conduct research for submission to EPA under the pesticide laws. If such research involves intentional exposure of human subjects, these individuals (respondents) are required to submit study protocols to the EPA and a cognizant local Human Subjects IRB before such research is initiated so that the

scientific design and ethical standards that will be employed during the proposed study may be reviewed and approved. Also, respondents are required to submit information about the ethical conduct of completed research that involved human subjects when such research is submitted to the EPA. This renewal ICR estimates the third-party response burden from complying with the requirements in 40 CFR part 26.

Form Numbers: None.

Respondents/affected entities: Any entities that submits to EPA under FIFRA and/or FFDCA protocols and study reports for environmental research involving human subjects.

Respondent's obligation to respond: Mandatory under 40 CFR part 26.

Estimated number of respondents: 10 (total).

Frequency of response: On occasion.

Total estimated burden: 8,276 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $859,215 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an estimated decrease of 1,966 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This decrease is a result of the anticipated number of responses per year for the next three years based on comments received from stakeholders. This change is an adjustment.

Courtney Kerwin

Director, Regulatory Support Division

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